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EP 1036551 A2 WO 99/55256 A1
WO 00/38591 A2

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(54) Abstract Title
Helical formations in tubes

(57) There is disclosed a method for introducing a helical formation into a flexible tubular material, comprising supporting the material together with a surrounding helical former so as to deform the material to have a helical indentation corresponding to the shape of the former, and setting the material in that configuration and removing the former.

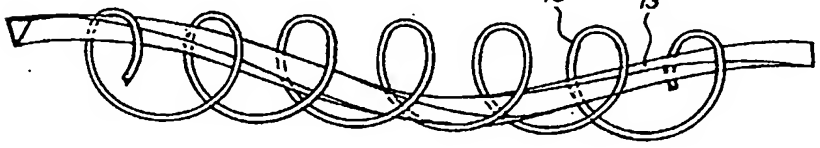

FIG. 4

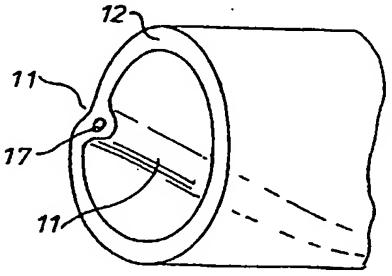

FIG. 5

GB 2 369 797 A

At least one drawing originally filed was informal.

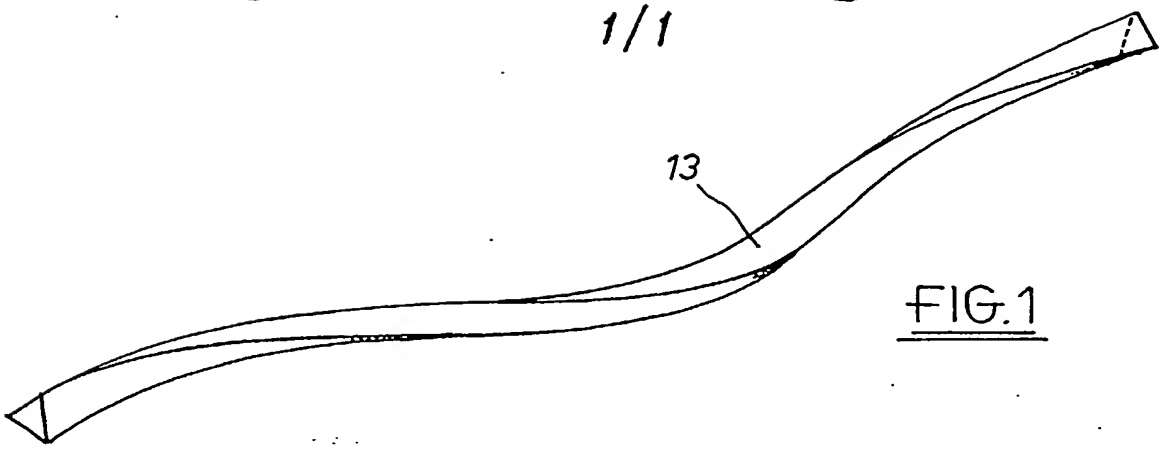

FIG.1

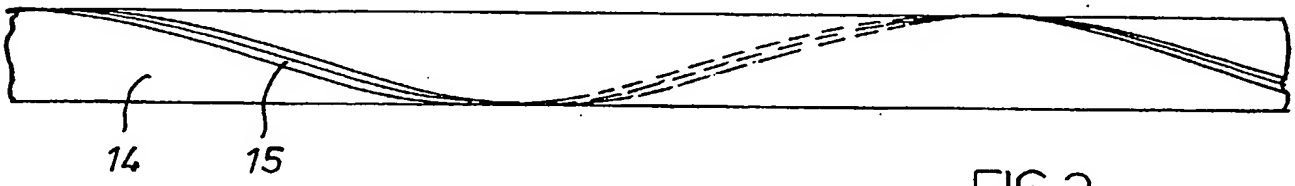

FIG.2

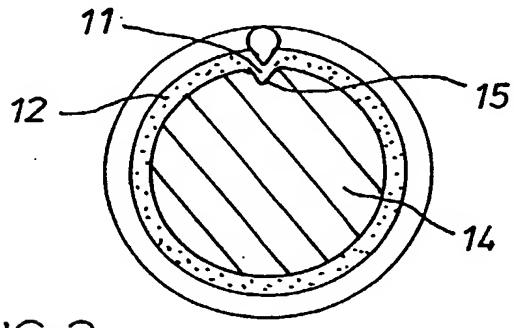

FIG.3

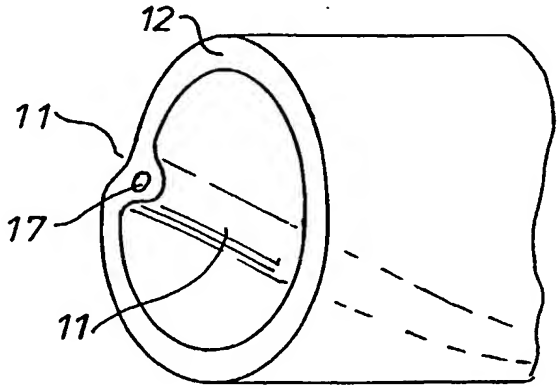

FIG.5

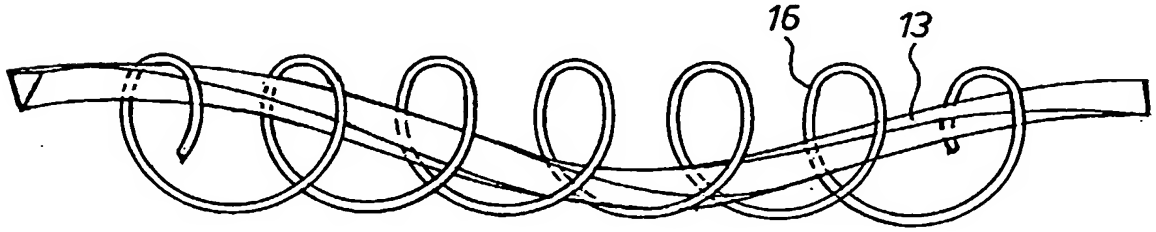

FIG.4

formation after the setting operation. The strand may be a monofilament or a multifilament strand. The strand may be secured by a subsequent coating.

The effect of the strand will be an extension of the finished prosthesis for implant, to introduce a modular formation to the prosthesis, mimicking natural blood vessels.

Methods of introducing a helical formation according to the invention will now be described with regard to the accompanying drawings, in which:

Figure 1 is a view of a helical former for use in the method;

Figure 2 is a view of a helically grooved mandrel for use in one method according to the invention;

Figure 3 is a cross-section through the mandrel of Figure 2, with the material and former in place;

Figure 4 is a view of a cage, with former in place, in a second method according to the invention; and

Figure 5 is a cross-section of a helically deformed tube with a filament insert.

The drawings illustrate a method for introducing a helical formation 11 into a flexible tubular material 12 comprising supporting the material 12 together with a surrounding helical former 13 so as to deform the material 12 to have a helical formation

corresponding to the shape of the former 13, and setting the material in that configuration and removing the former 13.

Figures 2 and 3 illustrate a method in which the tubular material is supported on a mandrel 14 with a groove 15 corresponding to the configuration of the helical former 13. The material 12 is effectively clamped between the mandrel 13 and the former 13, and forced into the groove 15.

Figure 4 illustrates a method in which the material 12 is supported in a surrounding structure 16 together with the former 13. The surrounding structure 16 is in the form of a helical wire cage.

The material 12 is of a thermoplastic or thermosetting polymer and the indentation can then be heat set.

Any other setting method may be used appropriate to the material, of course, including a chemical, infra-red or ultra-violet setting method - anything that initiates or effects cross-linking in a polymer will be a possibility.

However, it is desirable that, especially in the case of a vascular prosthesis, the finished product is elastically extensible, so as to be tensioned between the anastomoses. Generally, a tension resulting from a stretch of 10% of its maximum extensibility would be appropriate.

In order to guarantee that the correct helix angle of the indentation, namely the angle that gives, on theoretical, trial and error or whatever other appropriate grounds the best result in terms of the elimination of turbulent flow and dead flow areas in and

downstream of the implant, the material 12 can be pre-stretched for the indentation by the 10% or other appropriate amount.

The material 12 may be coated, after the indentation, for any reason. It may be that the material, which may, for example, be a woven or knitted polyamide or polyester, is coated with a biocompatible material such as a polyurethane.

A strand 17 may be incorporated into the indentation and sealed therein by a coating, which may be an overall coating, or a "local" coating or glue. The strand 17 may comprise a monofilament eg. of polyester, or it may be a multifilament strand. This will help to maintain the shape and integrity of the indentation, but can also have another effect, namely that on such extension as is required to give proper implant tension, the presence of the strand will imply an undulation to the tube, mimicking natural blood vessels.

Clearly, more than one helical "start" may be applied, as by having multiple helical formers or by applying a single such former two or more times each angularly displaced for all previous applications.

And, while the invention has been described particularly with reference to blood flow tubing and, more particularly, with regard to implants, it is possible to provide process plant pipework with internal spiral formations by similar means. In particular, if pipework is capable of deformation, it might well be given an internal helical formation by wrapping around it a helical former and pressing the former into the pipe, eg. by thermal contraction.

CLAIMS

1. A method for introducing a helical formation into a flexible tubular material, comprising supporting the material together with a surrounding helical former so as to deform the material to have a helical indentation corresponding to the shape of the former, and setting the material in that configuration and removing the former.

2. A method according to claim 1, in which the tubular material is supported on a mandrel with a groove corresponding to the configuration of the helical former.

3. A method according to claim 1, in which the material is supported in a surrounding structure together with the former.

4. A method according to any one of claims 1 to 3, in which the material is thermoplastic or thermosetting and is heat set.

5. A method according to any one of claims 1 to 4, in which the material is pre-tensioned during the introduction of the helical formation.

6. A method according to claim 5, in which the material is pre-tensioned to 10% of its maximum extensibility.

7. A method according to any one of claims 1 to 6, in which a coating is applied to the material after the setting operation.

8. A method according to claim 7, in which the coating is a polyurethane dispersion.

Helical Formations in Tubes

This invention relates to helical formations in tubes.

In WO 00/38591 is disclosed the concept of helical formations in tubes for the purpose of improving in certain desirable respects, the flow of fluid through them.

In particular, blood flow tubing, such as vascular grafts, can benefit markedly from internal helical formations such as ridges or grooves, which, if appropriately configured having regard to the tube dimensions and the density, viscosity and flow rate of blood therethrough, can eliminate turbulent flow and dead regions which can lead to plaque formation, which, in turn, can lead to reduced flow capacity or thromboses.

The present invention provides ways of introducing a helical configurations into tubing, particularly blood flow tubing, which facilitate the manufacture of the tubing to clinical standards.

The invention comprises a method for introducing a helical formation into a flexible tubular material, comprising supporting the material together with a surrounding helical former so as to deform the material to have a helical indentation corresponding to the shape of the former and setting the material in that configuration and removing the former.

The tubular material may be supported on a mandrel with a groove corresponding to the configuration by the helical former. The material is effectively clamped between the mandrel and the former.

However, the material may be supported in a surrounding structure together with the former - the surrounding structure may comprise a cage such as a wire helix.

Whilst, as compared to the multi-start helical formulations proposed in WO 00/38591, the method of the present invention is particularly adapted to the introduction of a single start helical formation, it is found that such a formation is remarkable effective. Of course, the method of the invention could readily be adapted to the introduction of multi-start helical formations, if required, either by having a multiple former arrangement or by using a single former repeatedly with an appropriate angular shift.

The tubular material may be thermoplastic or thermosetting, and the indentation heat set.

However, for vascular prostheses, it may be important to provide a degree of extensibility, so that the prosthesis may be under some tension between the anastomoses. Heat setting should leave the tubular material, therefore still elastically extensible.

In order to provide the correct helix angle in a prosthesis in its tensional configuration, the material may be pre-tensioned for the introduction of the indentation. A pre-tensioning such as will provide the best helix angle on a 10% of full extensibility extension is appropriate.

The material after the indentation has been set in can be coated with a biocompatible dispersion,, eg. with polyurethane. This may ensure that the internal surface of the tubular material maintains its shape.

A strand of a second material, which may have a different modulus of elasticity to the tubular material, may be introduced into and secured in the external helical

9. A method according to any one of claims 1 to 8, in which a strand of a second material having a different modulus of elasticity to the tubular material is introduced into and secured in the helical formation after the setting operation.

10. A method according to claim 9, in which the strand material comprises a monofilament.

11. A method according to claim 9, in which the strand material comprises a multifilament strand.

12. A method according to any one of claims 9 to 11, in which the strand is secured by applying an extend coating to the tubular material.

Application No:	GB 0127869.6	**Examiner:**	Damien J Huxley
Claims searched:	1 to 12	**Date of search:**	18 February 2002

Patents Act 1977
Search Report under Section 17

Databases searched:

UK Patent Office collections, including GB, EP, WO & US patent specifications, in:

UK Cl (Ed.T): A5R: RAR
B5A: ALX, ANA, AT10P, AT18P, AT21P, AT25P, ATXP
F2P: PC2, PC3, PC9, PM9

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B29D: 16/00, 23/00
F16L: 11/00, 11/08

Other: ONLINE: WPI, EPODOC, JAPIO

Documents considered to be relevant:

Category	Identity of document and relevant passage		Relevant to claims
A	EP 1036551 A2	(ANGIODYNAMICS) see whole document	
A	WO 00/38591 A2	(TAYSIDE) see the 2nd paragraph of page 9 and figure 3 in particular.	
A	WO 99/55256 A1	(INTRATHERAPEUTICS) see the whole document	

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention.
&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application.